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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/024,988	02/17/1998	RANDALL W. NELSON	5015C1	9007

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/024,988	NELSON ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-40 and 42-50* is/are pending in the application.

4a) Of the above claim(s) *32,34-39 and 42-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,33,40,47,48 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment filed December 9, 2005 is acknowledged. Claims 31-40 and 42-50 are pending. Claims 32, 34-39 and 42-47, drawn to non-elected inventions, are withdrawn from consideration.

Claims 31, 33, 40 and 48-50 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejection Maintained:

3. Claims 31, 33, 40 and 48-50 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31, 33, 37, 39, 44, 46 of copending Application No. 09/808,314, filed 3/14/2001.

Applicants have failed to address this rejection. The rejection is maintained for the reasons of record.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 431, 33, 37, 39, 44, 46 of copending Application No. 09/808,314 are drawn to methods for determining how much of, or the relative amount of, one or more certain antigens (or antibodies or analytes) are present in a sample, comprising the steps of adding an internal reference species (where the internal reference species binds to the same affinity reagent as the analyte) to the sample, and appears to comprise a step of using matrix-assisted laser

desorption/ionization (MALDI) mass spectrometry to quantify the signals of the antigens, antibodies or analytes together with the internal reference species (claim 31, for example, contains the step of "adding a laser desorption/ionization agent to the released one or more anlytes..."). Therefore, the claims of 09/808,314 appear to be encompassed by claims 31, 33, 40, and 48-50, because these claims are drawn to methods for quantifying analytes or proteins in a sample, comprising the addition of an internal reference species that binds to an affinity reagent that also binds to the analyte and the use of MALDI for analyzing and quantifying the analyte.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections Withdrawn:

4. The rejection of claims 31, 33, 40 and 48-50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

5. The rejection of claims 31, 33 and 40 under 35 U.S.C. 102(b) as being anticipated by Gaskell and Brownsey (Clin. Chem., 29(4): 677-680, 1983), Gaskell (Steroids, 55: 458-462, 1990), Bonfanti (Cancer Research, 50: 6870-6875, 1990) or Davoli (Anal. Chem., 65: 2679-2685, 1993) is withdrawn in view of the amendment to the claims.

6. The rejection of claims 31, 33, 40 and 48-50 under 35 U.S.C. 102(b) as being anticipated by Lisek (Lisek, C.A. et al. Rapid Communications in Mass Spectrometry 3(2): 43-46, 1989;) is withdrawn in view of the amendment to the claims

New Grounds of Rejection:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 31, 33, 40, 48, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan (Duncan, M.W. et al., Rapid Communications in Mass Spectrometry, 7: 1090-1094, 1993) in view of Nuwaysir (Nuwaysir, L.M., et al. J. Am. Soc. Mass Spectrom., 4: 662-669, 1993).

Duncan teaches the use of internal standards, where the internal standards may be isotopically labeled analogues of an analyte (falls within scope of "modified analyte with shifted molecular weight"), to overcome the difficulties of using MALDI for quantitative analysis of analytes (see page 1090, 1st to 2nd column). Duncan also teaches the use of a working curve and the substeps of claims 40 and 50 (see page 1092, 2nd column, Figure 2). Duncan also teaches that "real" samples require prior clean-up by, for example, immunoaffinity separation or chromatography (see page 1094). Duncan fails to demonstrate the method with real samples using any type of affinity reagent.

However, Nuwaysir teaches a method of using metal-ion affinity chromatography to purify samples before they are analyzed by MALDI (see page 663, 1st column, last paragraph and page 665, 1st column, 3rd paragraph, see page 668, Figure 6). The samples are of phosphopeptides, which is encompassed by the term "protein" in claims 48-50.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Duncan on the use of isotopically labeled internal standards for quantification with MALDI with those of Nuwaysir on

the use of affinity chromatography for the purification of samples prior to MALDI. The motivation to combine the teachings is provided by Duncan, which demonstrates the advantages of using internal standards when one wants to quantify an analyte, and is provided by Nuwaysir in the teachings that prior purification of samples with affinity chromatography is necessary for mass spectrometry of samples with a large number of peptides (see page 663, 1st column, 2nd paragraph).

8. Claims 31, 33, 40, 48, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan (Duncan, M.W. et al., Rapid Communications in Mass Spectrometry, 7: 1090-1094, 1993) in view of Hutchens (US 6,528,320; Mar. 4, 2003; effective filing date May 28, 1993).

Duncan teaches the use of internal standards, where the internal standards may be isotopically labeled analogues of an analyte (falls within scope of "modified analyte with shifted molecular weight"), to overcome the difficulties of using MALDI for quantitative analysis of analytes (see page 1090, 1st to 2nd column). Duncan also teaches the use of a working curve and the substeps of claims 40 and 50 (see page 1092, 2nd column, Figure 2). Duncan also teaches that "real" samples require prior clean-up by, for example, immunoaffinity separation or chromatography (see page 1094). Duncan fails to demonstrate the method with real samples using any type of affinity reagent.

However, Hutchens teaches a method of capturing an analyte from a sample on a sample presenting surface derivatized with an affinity reagent that binds the analyte, wherein the affinity reagent is a metal ion, a protein , a peptide, a nucleic acid or a dye, followed by detecting the

capture analyte by laser desorption/ionization mass spectrometry (see claim 1, column 14). The analyte may be a protein (see claim 11, column 15).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Duncan on the use of isotope-labeled internal standards for quantification with MALDI with those of Hutchens on the use of affinity reagents for the purification of samples prior to MALDI. The motivation to combine the teachings is provided by Duncan, which demonstrates the advantages of using internal standards when one wants to quantify an analyte, and is provided by Hutchens in the teachings that prior purification of samples with an affinity reagent is necessary for mass spectrometry of samples (column 1, line 56 –65).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
March 1, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER